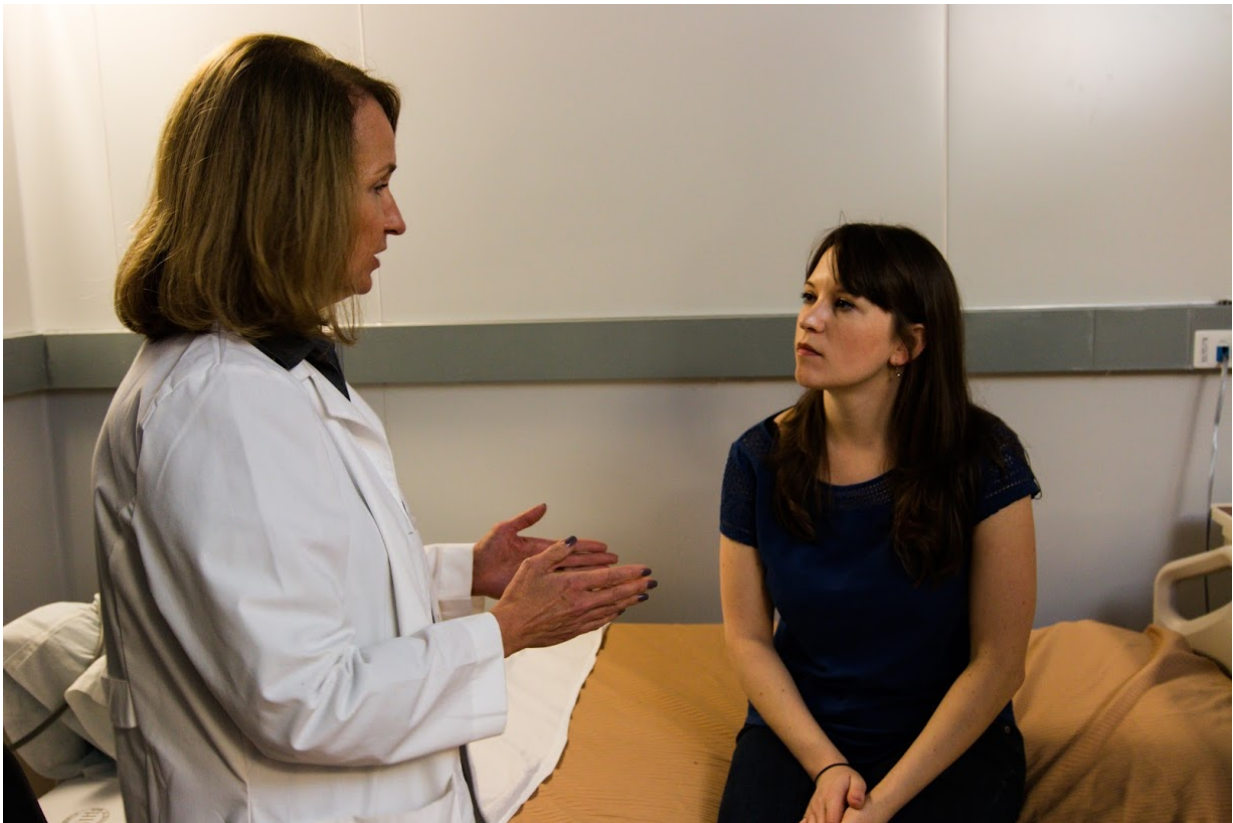


Islet transplantation restores blood sugar awareness and control in type 1 diabetes

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Credit: NIDDK

New clinical trial results show that transplantation of pancreatic islets—cell clusters that contain insulin-producing cells—prevents severe, potentially life-threatening drops in blood sugar in people with

type 1 diabetes. Researchers found that the treatment was effective for people who experienced episodes of severe hypoglycemia—low blood sugar levels that can lead to seizures, loss of consciousness and death—despite receiving expert care.

The Phase 3 trial was funded by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), both part of the National Institutes of Health, and was conducted by the NIH-sponsored Clinical Islet Transplantation (CIT) Consortium. The investigators designed the study in consultation with the U.S. Food and Drug Administration to enable potential future licensure of the manufacture of purified human pancreatic islets. The results appear online today in *Diabetes Care*.

"The findings suggest that for people who continue to have life-altering severe hypoglycemia despite optimal medical management, [islet transplantation](#) offers a potentially lifesaving treatment that in the majority of cases eliminates severe hypoglycemic events while conferring excellent control of blood sugar," said NIAID Director Anthony S. Fauci, M.D.

As expected, the treatment carried risks, including infections and lowered kidney function as a result of people taking the immune-suppressing drugs needed to prevent rejection of the donor islets. Although some of the side effects were serious, none led to death or disability. In the United States, islet transplantation is currently available only in clinical trials.

"While still experimental, and with risks that must be weighed carefully, the promise of islet transplantation is undeniable and encouraging," said NIDDK Director Griffin P. Rodgers, M.D. "Even with the best care, about 30 percent of people with type 1 [diabetes](#) aren't aware of dangerous drops in blood glucose levels."

In type 1 diabetes, the immune system attacks and destroys insulin-producing cells in the islets of the pancreas. People with type 1 diabetes need lifelong treatment with insulin, which helps transport the sugar glucose from the bloodstream into cells, where it serves as a key energy source. Even with insulin therapy, people with type 1 diabetes frequently experience fluctuations in [blood sugar levels](#).

Hypoglycemia, or low blood sugar, typically is accompanied by symptoms such as tremors, sweating and heart palpitations that prompt people to eat or drink to raise their [blood sugar](#) levels. Those who do not experience these early warning signs—a condition called impaired awareness of hypoglycemia—are at increased risk for severe hypoglycemic events, during which the person is unable to treat himself or herself. Treatments such as behavioral therapies or continuous glucose-monitoring systems can prevent these events in many—but not all—people with this impaired awareness, leaving a substantial number of people at risk.

The current study enrolled 48 people who had persistent impaired awareness of hypoglycemia and experienced severe hypoglycemic events despite expert care by a diabetes specialist or endocrinologist.

Investigators at eight study sites in North America used a standardized manufacturing protocol to prepare purified islets from the pancreases of deceased human donors. All [study participants](#) received at least one transplant of islets injected into the portal vein, the major vessel that carries blood from the intestine into the liver. Islet recipients currently must take immunosuppressive drugs for the rest of their lives to prevent their immune systems from rejecting the transplanted cells.

One year after the first transplant, 88 percent of study participants were free of severe hypoglycemic events, had established near-normal control of glucose levels, and had restored hypoglycemic awareness. After two years, 71 percent of participants continued to meet these criteria for

transplant success.

Even a small number of functioning, insulin-producing cells can restore hypoglycemic awareness, although transplant recipients may need to continue taking insulin to fully regulate [blood glucose levels](#). Participants who still needed insulin 75 days after transplant were eligible for another islet infusion. Twenty-five participants received a second transplant, and one received three. After one year, 52 percent of study participants no longer needed insulin therapy.

"This is the first license-enabling trial of a cellular product for treatment of type 1 diabetes," said NIAID Transplantation Branch Chief Nancy D. Bridges, M.D., a co-author of the paper. "Licensure is critical because it will ensure the quality, consistency and safety of the islet product; provide greater patient access to islet transplantation; and accelerate continued research that we hope would make this procedure suitable for a broader population of people with type 1 diabetes."

The researchers are [continuing to follow](#) participants to determine whether the benefits of restoring near-normal blood glucose control and protection from severe hypoglycemic events will outweigh the risks associated with chronic immunosuppression.

"For people unable to safely control type 1 diabetes, islet transplantation offers real hope for preventing severe, life-threatening hypoglycemia," said study co-author Tom Eggerman, M.D., Ph.D., NIDDK scientific officer for the CIT Consortium. "However, as immunosuppression drugs required for transplantation can have significant adverse side effects, the treatment only makes sense for people who have frequent severe hypoglycemia despite optimal diabetes management, or for those already on immunosuppressant drugs for a kidney transplant, a group being studied in another [Phase 3 trial](#)."

Provided by NIH/National Institute of Allergy and Infectious Diseases

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